K041380

JUN - 8 2004

510(k) Summary of Safety and Effectiveness
Prepared April 16, 2004

Submitted by: R2 Technology, Inc.
1195 W. Fremont Avenue
Sunnyvale, CA 94087

Contact Person: Kathy O'Shaughnessy
Vice President, Regulatory Affairs

Product Name: ImageChecker CT Software Package with Filling Defect Indicator

Common Name: Medical Image Processing Software

Classification Panel: Radiology

Classification: Class II (CFR 21 892.2050)

Product Code: LLZ

Predicate Devices:

Product	Company	510(k) Number
LungCARE CT software package with extended functionality	Siemens Medical Solutions	K033374
ImageChecker CT Workstation	R2 Technology, Inc.	K023003

Device Description:

The ImageChecker CT Software Package with Filling Defect Indicator (FDI), the subject of this notification, is a thoracic image visualization and analysis tool. This tool offers an extended functionality of the ImageChecker CT Workstation, utilizing segmentation techniques similar to the two above-mentioned predicates. Based on physician request, the FDI tool automatically segments locations in the vasculature of the chest containing

low densities that typically correlate with filling defects. The process is based on simple segmentation methodology applied to contrast-opacified CT images of the chest identifying regions of connected voxels below a certain HU (Hounsfield Unit) threshold. A low density region is highlighted by placing a triangle on the region of the vascular structure of interest. This extended software functionality is designed for use with the existing tool set present on the R2 ImageChecker CT Workstation (K023003) and on other CT workstations that utilize the ImageChecker CT Workstation software tools. The FDI tool contains modifications to the Workstation with a special workflow based on automated segmentation for the visual identification of possible lung filling defects.

Summary of Intended Use:

The ImageChecker CT Software Package with Filling Defect Indicator is intended to be used to enable the radiologist to view and analyze regions of the image containing low density within vascular structures that may be indicative of filling defects or other intravascular abnormalities. This segmentation tool is an extended functionality of the R2 ImageChecker CT Workstation software, and can be used on that self-standing device as well as other imaging workstations that utilize the ImageChecker CT Workstation software. This tool is intended for use as an adjunctive device that assists the radiologist in the review of CT images of the chest.

Comparison with Predicate Devices:

R2 Technology's ImageChecker CT Software Package with Filling Defect Indicator (FDI) software tool, Siemens LungCARE CT software package with extended functionality, and the R2 ImageChecker CT Workstation enable radiologists to view and analyze areas of CT exams. These software packages allow the radiologist to examine segmented candidate regions of interest in the CT volume data sets. The three software packages also enable the radiologist to document and follow up any identified segmented areas of interest.

The Siemens LungCARE CT Software Package with Extended Functionality is a self contained software package containing the specifically developed function of supporting a special workflow based on automated segmentation for the visual identification of possible lesions (Nodule Enhanced Viewing). Likewise, R2's ImageChecker CT Software Package with Filling Defect Indicator is built on the base ImageChecker CT Workstation software with a special workflow based on automated segmentation for the visual identification of possible filling defects of the lung vasculature (FDI).

Studies:

The Filling Defect Indicator tools package will undergo design verification tests for conformance with specifications.

Conclusion:

The ImageChecker CT Software Package with Filling Defect Indicator has the same intended use as the two predicate devices identified in this section. Any technological differences in the ImageChecker CT Software Package with Filling Defect Indicator and the predicate devices do not raise any new questions regarding safety or effectiveness. Thus, R2 Technology's ImageChecker CT Filling Defect Indicator (FDI) software tool is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 11 2009

R2 Technologies, Inc.
% Ms. Denise Leung Klinker
Reviewer, Medical Device Services
Underwriters Laboratories, Inc.
1655 Scott Boulevard
SANTA CLARA CA 95050-4169

Re: K041380
Trade/Device Name: ImageChecker CT Software Package with Filling Defect Indicator
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: OEB
Dated: May 24, 2004
Received: May 25, 2004

Dear Ms. Klinker:

This letter corrects our substantially equivalent letter of June 8, 2004.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801; good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding os substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.suppot/index.html.

Sincerely yours,

for Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number K041380

Device Name: ImageChecker CT Software Package with Filling Defect Indicator

Indications for Use:

The ImageChecker CT Software Package with Filling Defect Indicator (FDI) is used during the review of contrast-enhanced computed tomography (CT) images of the chest. This software tool enables the radiologist to view and analyze regions of the image containing low density within vascular structures that may be indicative of filling defects or other intravascular abnormalities.

The software is designed to assist the radiologist in characterization and classification of these suspicious candidate thoracic abnormalities in terms of density, size, dimension, shape and position, thus aiding in the patient management care decision process.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K041380